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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709			EXAMINER RAMANA, ANURADHA	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 09/20/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/603,471

Applicant(s)

GAUSE ET AL.

Examiner

Anu Ramana

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 September 2007.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38, 59-62 and 81-93 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-38, 59-62 and 81-93 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 5-11, 20-27 and 83-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 5, 20 and 83, the use of "first and second members" is misleading since Applicants' appear to be claiming the geometry of the visualization opening. It is suggested that Applicants use an alternative term such as "portion" instead of "member" to avoid confusion.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-14, 18, 20-22, 81-88, 92 and 93 are rejected under 35 U.S.C. 102(e) as being anticipated by Haider (US 2003/0105462 A1).

Haider discloses an elongate bone plate including an opening or "a visualization opening" having an hourglass shape with convexly and concavely curved side walls (Fig. 2 and paras [0027]-[0034]).

Claims 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Coates et al. (US 5,423,826).

Coates et al. disclose a plating system including a plate 22 with two bone fastener holes, a holding instrument with a guide mechanism including a guide member 180 spaced proximally from the plate when the holding system is engaged with the plate and a laterally extending alignment member 159 (Figs. 10, 14, 17 and 19, col. 10, lines 36-68, col. 11, lines 1-48, col. 12, lines 67-68 and col. 13).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haider (US 2003/0105462 A1).

Haider discloses all elements of the claimed invention except for the claimed widths and length-to-width ratios.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a visualization opening with the claimed length-to-width ratios, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 1-15, 18-27, 81-88, 92 and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lyons et al. (US 6,413,259).

Lyons et al. disclose a bone plate 12 including a visualization openings 28; first and second anchors 22 on each side of the visualization openings; and retaining

devices 22 to prevent the bone anchors from backing out of the plate (Figs. 1-3, col. 4, lines 43-67, cols. 5-6 and col. 7, lines 1-36).

Lyons et al. disclose all elements of the claimed invention except for: (1) an hour-glass shape of the visualization opening; (2) the curvatures of the side walls of the visualization opening; and (3) the widths and length-to-width ratios of the visualization opening.

It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to have provided the visualization opening with the claimed shapes of the walls, since applicant has not disclosed that this solves any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purpose of providing a visualization opening. In re Dailey and Eilers, 149 USPQ 47 (1966).

It would have also been obvious to one having ordinary skill in the art at the time the invention was made to have provided a visualization opening with the claimed length-to-width ratios, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 16-17, 28-35 and 89-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lyons et al. (US 6,413,259) in view of Michelson (US 6,193,721).

Lyons et al. disclose all elements of the claimed invention except for: (1) a holding instrument to hold the plate; and (2) the claimed shape of the visualization opening.

Michelson teaches a type of plate holder to hold a plate in position wherein the plate holder has an actuating system; first and second holding members to selectively engage the plate; and a guide mechanism including a guide member 54 positioned relative to the plate (Fig. 39, col. 20, lines 48-53, col. 21, lines 56-67 and col. 22, lines 1-51).

It would have been obvious to one of ordinary skill in the art to have utilized a plate holder as taught by Michelson to hold the Lyons et al. plate since it was well known in the art to use a plate holder to position a plate against bone.

The combination of Lyons et al. and Michelson teaches all elements of the claimed invention except for the claimed shapes of the walls of the visualization opening.

It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to have provided the visualization opening with the claimed shapes of the walls, since applicant has not disclosed that this solves any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purpose of providing visualization opening. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claims 1-15, 18, 20-27, 92 and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bono et al. (US 5,954,722).

Bono et al. disclose an elongate bone plate 50 with a visualization opening 59 (col.3, lines 48-67, cols. 4-6 and col. 7, lines 1-49).

Bono et al. disclose all elements of the claimed invention except for: (1) the visualization opening having an hourglass shape; (2) concave/convex curvatures of the visualization opening walls; and (3) the claimed widths and the length-to-width ratios.

It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to have provided the visualization opening with the claimed shapes of the walls, since applicant has not disclosed that this solves any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purpose of providing visualization opening. In re Dailey and Eilers, 149 USPQ 47 (1966).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a visualization opening with the claimed length-to-width ratios, since it has been held that where the general conditions of a claim are

disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bono et al. (US 5,954,722) in view of Boucher et al. (US 6,514,274).

Bono et al. disclose all elements of the claimed invention except for the plate being made of a material that is translucent.

Boucher et al. teach making a plate of a translucent material to enable visual alignment of the plate with holes in the underlying bone (col. 4, lines 14-30).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the Bono et al. plate of a translucent material as taught by Boucher et al., to enable visual alignment of the plate with underlying bone holes.

Claims 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over in Lyons et al. (US 6,413,259) view of Boucher et al. (US 6,514,274).

Lyons et al. disclose all elements of the claimed invention except for the plate being made of a material that is translucent.

Boucher et al. teach making a plate of a translucent material to enable visual alignment of the plate with holes in the underlying bone (col. 4, lines 14-30).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the Lyons et al. plate of a resorbable, translucent, material as taught by Boucher et al., to enable visual alignment of the plate with underlying bone holes.

### ***Response to Arguments***

Applicants' arguments submitted under "REMARKS" in the response filed on September 11, 2007 have been fully considered.

After consideration of Applicants' request to withdraw the finality of the previous action, the Examiner is withdrawing the finality of the previous action and making the present office action final.

Applicants' arguments with respect to the rejections of claim 5-11, 20-27 and 83-88 under 35 USC 112 second paragraph are persuasive. Accordingly, the Examiner is withdrawing the rejection.

The rejections of claims 1-14, 18, 20-22, 81-88, 92 and 93 are not overcome since an affidavit has not been provided. It is also noted that although claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26USPQ2d 1057 (Fed. Cir. 1993).

Regarding the rejections of claims 36-38 under 35 USC 102(b) as being anticipated by Coates et al. (US 5,423,826), contrary to Applicants' statements on page 18, the Examiner carefully considered the arguments presented in the response filed on May 7, 2007 and found them not persuasive. See comments in the previous office action.

Regarding Applicants' arguments with respect to the various rejections under 35 USC 103(a) over Lyons et al., and Bono et al. either alone or in combination with other references, the Examiner notes that Applicants' disclosure as originally filed states that the visualization openings 60 can take other shapes (paras [0056] and [0059]). Accordingly, there is no criticality to providing an hour-glass shape to visualization openings 60.

Regarding Applicants' arguments with respect to the rejections of 59-62 under 35 USC 103(a) over Bono et al. in view of Boucher et al. and separately, over Lyons et al. in view of Boucher et al., it is noted that a person of ordinary skill in the art has good reason to use translucent material as taught by Boucher et al., as the material of construction for the Bono et al. plate or Lyons et al. plate, in order to obtain the predictable result of increased visibility of underlying bone.



**Conclusion**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR  
September 19, 2007

  
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